REMARKS

Claims 1-6 and 8-15 are pending. Claims 8-13 have been withdrawn. Claim 15 has been newly added. Claims 1 and 15 are in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Initially, Applicants wish to address an issue raised in the Office Action concerning the dissolution rate test discussed in the specification. Specifically, the Office Action alleges that the dissolution rate test does not provide a temperature at which the testing is performed.

On page 1 of the specification, the last sentence indicates that testing was conducted in accordance with the United States Pharmacopeia (USP), Type II Apparatus set at 50 rpm. While not stated in the specification, Applicants note that the USP testing protocol stipulates that dissolution rate testing is to be performed at a temperature of 37 °C. As such, it is respectfully submitted that the testing temperature of 37 °C is understood.

Rejections Under 35 USC § 103

Claims 1-6 and 14 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,486,436 ("Sunshine et al."), U.S. Patent No. 4,943,565 ("Tencza et al."), Remington's Pharmaceutical Sciences p. 1837 ("Remington"), U.S. Patent No. 6,602,520 ("Schroeder et al.") and WO 01/87264 ("Jain et al.). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Claim 1 is directed to a solid pharmaceutical dosage form that includes among its noteworthy features, caffeine, wherein the caffeine is in the form of uncoated ungranulated particles having a granular morphology and an average particle size of about 70 to 600 microns, and wherein at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

Applicants submit with this Amendment, a Declaration from one of the inventors, Christopher Szymczak, which explains the difference between the terms "granular" and "granulated." Mr. Szymczak explains that the two terms have different meanings in industrial pharmacy (e.g. pharmaceutics). "In pharmaceutics terms, "granular" refers to a type of particle of a composition, which comprises one kind of material (relatively pure chemical), or one sole

type of particle, often a singular crystalline particle of relatively larger particle size compared to a powder form." (See Declaration Under 37 CFR 1.132 submitted by Christopher E. Szymczak, paragraph 5). Mr. Szymczak further explains that the term "granulated" or "granulation" refers to an agglomerate formed through compression or wetting of the surface (i.e., wet granulation) containing multiple components in powder form often using one or more chemical binders or other materials, which are capable of binding particles and usually contains a disintegrant to enhance disintegration (thereby increasing the dissolution rate).). He concludes by stating that the two terms relate to different concepts. (See Declaration Under 37 CFR 1.132 submitted by Christopher E. Szymczak, paragraph 5).

Applicants have noted that the inventive dosage form contains uncoated ungranulated caffeine particles, which have a granular morphology. The caffeine particles are relatively pure chemically. And they have a larger particle size when compared to caffeine powder. The caffeine particles are not granulated. Using caffeine of this type (uncoated ungranulated particles having a granular morphology and an average particle size of about 70 to 600 microns) is one of the reasons that Applicants are able to achieve superior dissolution rates.

Applicants have reviewed the disclosures of Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences, Schroeder et al. and Jain et al., and have not found these references to disclose or suggest the inclusion of uncoated ungranulated particles of caffeine having a granular morphology and an average particle size of about 70 to 600 microns. Nor do any of these references disclose or suggest a solid dosage form containing caffeine, where at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

Only Applicants inventive dosage form as recited in Claim 1, demonstrates such a dissolution rate. Applicants have found that the inclusion of uncoated ungranulated caffeine particles having a granular morphology and an average particle size of about 70 to 600 microns helps in achieving such superior results.

As such, Claim 1 is patentable over the proposed combination of Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), Schroeder et al. and Jain et al.

Newly added independent Claim 15 is very similar to Claim 1, except that Claim 15 stipulates that about 5 mg to about 400 mg of caffeine are included in the dosage form. For at least the same reasons discussed above for Claim 1, Claim 15 is patentable over the proposed combination of Sunshine et al., Tencza et al., Remington, and Schroeder et al. and Jain et al.

Claims 2-6 and 14, directly or indirectly depend from Claim 1. For at least the same reasons discussed above for Claim 1, Claims 2-6 and 14 are patentable over the proposed combination of Sunshine et al., Tencza et al., Remington, and Schroeder et al. and Jain et al.

Conclusion

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Victor Tsu/

_____

Attorney for Applicants
Victor Tsu
Registration No. 46,185

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003